

EFFICACY REVIEW

PRODUCT: SVP7

FILE SYMBOL: 83399-A

DATE: 06/26/07

DP BARCODE: D340868

DECISION NUMBER: 373247

GLP: N/A

CHEMICAL: Permethrin (36.08%)
Dinotefuran (4.95%)
Pyriproxyfen (0.44%)

CHEMICAL NUMBER: Permethrin.....109701
Dinotefuran.....044312
Pyriproxyfen....129032

PURPOSE: Review of rebuttal to efficacy review dated June 14, 2007.

MRID: N/A

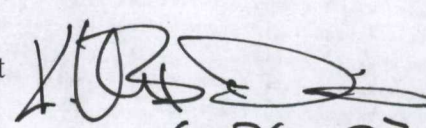
TEAM REVIEWER: Rita Kumar

EFFICACY REVIEWER: Kable Bo Davis, M.S., Entomologist

BACKGROUND:

SVP7 is intended for the treatment and prevention of ticks, fleas, and mosquitoes on dogs and puppies over seven weeks of age. The application rate is: 0.06 fl oz for weights 2.5 to 20 lbs., 0.12 fl oz for weights 20 to 55 lbs, 0.16 fl oz for weights 56 to 95 lbs, and 0.3 fl oz for over 95 pounds. The directions for use state that to part the hair between the shoulder blades and to slowly apply the product to the skin until the applicator is completely empty. The number of spots to apply varies upon the weight of the dog. The product should be repeated monthly, and must never be used on other animals, including cats.

A rebuttal to an Agency efficacy review (D340612; 373247) and the corresponding label were submitted to the Agency on June 20, 2007.


6-26-07

RECOMMENDATIONS:

1. All references to lice must be deleted from the label. To have lice added back on, acceptable efficacy data must be submitted or cited.
2. The medical impact of the disease anaplasmosis is questionable. All references to the disease must be deleted from the label.
3. Speed of kill efficacy data for pests infesting dogs weighing over 95 pounds can not be bridged from dogs weighing less. In an Agency efficacy review dated April 5, 2007 no data for mosquitoes were submitted for dogs weighing over 95 pounds. In addition, the following results for fleas and ticks were recorded:

Table 1. Efficacy of Spot-On Formulations Against Cat Fleas

DAT ¹	Control (mean count)	Percent Mortality		
		Low Dose	Medium Dose	High Dose
2	54.4	99.2%	99.8%	98.2%

Table 2. Efficacy of Spot-On Formulations Against Brown Dog Ticks

DAT ¹	Control (mean count)	Percent Mortality		
		Low Dose	Medium Dose	High Dose
2	21.5%	46.4%	62.1%	66.3%

Ticks
no speed
claims.

The following claims must be deleted from the label or include a disclaimer stating that they do not apply to dogs weighing over 95 pounds.

- "Kills 96% of fleas in 6 hours"
- "Quick onset of activity (kill) within 2 hours"
- "Kills newly emerged fleas before they lay eggs"
- "SVP7 contains dinotefuran, a "NEW (first 6 months) neonicotinoid insecticide with knockdown in less than 2 hours"
- "Dinotefuran kills fleas within 6 hours"
- "Kills fleas, ticks, lice and mosquitoes before they lay eggs"
- "Kills over 95% of fleas in 6 hours and up to 100% in 12 hours"
- "Kills fleas before they lay eggs"
- "Kills and repels fleas before they lay eggs"
- "Kills and repels ticks within 24 hours"
- "Kills ticks [in 24 – 48 hours] before they can transmit Lyme disease"
- "Kills ticks [in 24 – 48 hours] before they can transmit Ehrlichia"
- "Kills ticks before they can lay eggs"
- "Repels and kills up to 100% of mosquitoes for at least one month"

95+ lbs.